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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---------------------|-------------------------------|----------------------|-----------------------|------------------|--|
| 10/613,633 | 07/03/2003 | Eric M. Weaver | I. Weaver 1828.023US2 | | |
| | 90 01/04/200 LUNDBERG, WOE | EXAMINER | | | |
| P.O. BOX 2938 | | KIM, YUNSOO | | | |
| MINNEAPOLIS, | , MN 55402 | ART UNIT | PAPER NUMBER | | |
| | | 1644 | | | |
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| SHORTENED STATUTORY | PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 3 MONT | THS | 01/04/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | Application | No. | Applicant(s) | | | |
|--|--|--------------------|---------------|-------------------------|--------------------|-------------|--|--|
| | | 10/613,633 | | WEAVER ET AL. | | | | |
| Office Action Summary | | | Examiner | | Art Unit | | | |
| _ | | | Yunsoo Kim | | 1644 | | | |
| Period fo | The MAILING DATE of this commur or Reply | nication appe | ears on the c | over sheet with the c | orrespondence ad | ldress | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | |
| Status | | | | | | | | |
| 1) | Responsive to communication(s) file | ed on 29 Se | ptember 20 | <u>06</u> . | | | | |
| • — | · | 2b) ☐ This a | | | | • | | |
| 3) | Since this application is in condition | for allowand | ce except fo | r formal matters, pro | secution as to the | e merits is | | |
| , — | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositi | on of Claims | | | | | | | |
| 4) 🖂 | Claim(s) <u>9-18,20 and 21</u> is/are pend | ding in the a | pplication. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | • | | |
| 6)⊠ | Claim(s) <u>9-18, 20-21</u> is/are rejected | . | | | | | | |
| 7) | Claim(s) is/are objected to. | | | • | | | | |
| 8)□ | Claim(s) are subject to restri | ction and/or | election req | uirement. | | | | |
| Applicati | on Papers | | | | | | | |
| 9)[| The specification is objected to by the | ne Examiner | • | | | | | |
| 10) | The drawing(s) filed on is/are | : a) <u>□</u> acce | epted or b) | objected to by the E | Examiner. | • | | |
| ٠ | Applicant may not request that any object | ection to the d | drawing(s) be | held in abeyance. See | e 37 CFR 1.85(a). | • | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| Priority (| ınder 35 U.S.C. § 119 | | | | • | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | | |
| 1. ☐ Certified copies of the priority documents have been received. | | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| | | | | | | • | | |
| Attachmen | nt(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | | | | |
| | ce of Draftsperson's Patent Drawing Review (mation Disclosure Statement(s) (PTO/SB/08) | | 5 | i) Notice of Informal F | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | | | |

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DETAILED ACTION

- 1. Claims 9-18, 20 and 21 are pending.
- 2. In view of Applicants' amendment to the claims and arguments, the following rejection remains.
- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 9-18, 20 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,096,244 (of record) in view of U.S. Pat. No. 5,372,811 (of record), U.S. Pat. No. 5,143,257, (of record) and the evidence disclosed in p. 10 of the specification for the reasons set forth in the office action mailed 6/29/06.

Applicants' arguments and the declarations by Campbell and Weaver filed 9/29/06 have been fully considered but they were not found persuasive.

Applicants traversed the rejection based on that the combination of teachings does not result the claimed invention because the claimed invention solved the difficulties of administering by conventional water supply by removing fibrin from immunoglobulin containing plasma.

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Applicants' traversed the rejection based on that Applicants' declarations show unexpected result attributable to Applicant's claimed method to improve weight gain.

However, the declarations by Campbell and Weaver are not commensurate with the scope of the claimed invention. The claimed invention is drawn a method of improving weight gain by administering a stable immunoglobulin concentrate is administered to pigs by introducing in their water source. The compositions of declarations are plasma proteins and are not limited to immunoglobulins.

In addition, the defribinated plasma is produced by addition of calcium which promotes clotting and the immunoglobulin concentrate taught by the '244 patent is also defibrinated (col. 3, lines 7-18, in particular).

The '244 patent teaches administration of blood-derived immunoglobulin in a supplement to a young piglet (col. 3-4, Example 1, in particular), the immunoglobulin is pooled from serum of swine or cattle (col. 3, lines 1-3, in particular) and decreases mortality (col. 6, table 1, % survival increased, in particular).

The '244 patent further teaches the immunoglobulin comprises at least 15% by weight and is water miscible and stable (col. 3, lines 54-55, e.g. in aqueous mixture, col. 4, lines 16-42, in particular). In addition, the '244 patent teaches the supplement further comprises additives for example, vitamin or mineral (col. 4, lines 15-36, col. 5, lines 38-44, in particular), in aqueous mixture (col. 4, lines, 16-42, in particular).

The '244 patent further teaches administration of 0.5g immunoglobulin/hd/day or more (1g to 3g, col. lines 39-43, in particular) to animal of at any stage of animal's life (e.g. from day one to 21st day, col. 5-6 under example 1, in particular) in an immunoglobulin concentration of about 0.75% in water (e.g. 15 parts of dried serum in 100 parts aqueous mix, 1/5th of the serum protein consists of immunoglobulin, and the IgG concentration would be less).

Claim 13 has been included in this rejection because the specification of the instant application on p. 10, 1st paragraph discloses young, post weaning piglets are underweighted. Thus, post weaning piglets have been considered underweight.

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The '244 patent does not teach administering the immunoglobulin supplement via water source.

However, the '811 patent teaches the serum derived protein composes of albumin and immunoglobulin. The serum derived protein works to increase weight gain and feed efficiency of young pigs (col.2, lines 31-47, col. 3, lines 30-35, in particular). Thus, the referenced blood-derived immunoglobulin improves weight gain.

Furthermore, the '811 patent teaches the plasma proteins which are commensurate with the plasma proteins that are used in the studies described in the declarations (section 7 of Weaver declaration), the limitations of 35-50% of IgG as in claim 10 has been included in this rejection.

The '257 patent teaches the mixing of nutrients (e.g. water soluble supplement) in "drinking water" supply is common practice in livestock or farming industry to ensure good health at maturity. In this manner, the livestocks readily avoid common ailments that could cause premature death while dispensing in controlled dosages to the various animals to avoid potential adverse effects from overdosing. It is also essential for the commercial well being of the farmer as well. The liquid dispensing system in the farm industry is well known in the art (col. 1, lines 10-33, claims 1-13, in particular).

As the supplement may be mixed in "drinking water", it will not be provided via animal's feed sources or milk replacement.

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to administer blood-derived immunoglobulin supplement to improve weight gain and growth as taught by the '811 patent while decreasing morbidity and mortality as taught by the '244 patent in drinking water as a direct water source as taught by the '257 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '257 patent teaches that it is a common practice to mix nutrients in drinking water and provide as direct water source to various animals to avoid any potential adverse effects from overdosing while controlled dispensing (e.g. liquid dispenser) improves commercial well being of the farmers as well.

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From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

- 5. The following new ground of rejection is necessitated by Applicants' amendment filed 9/29/06.
- 6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.
- 7. Claims 9-18, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification and the claims as originally filed do not provide a clear support for the phrase "from which the fibrin has been separated" and applicant has not pointed out where the support comes from.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. No claims are allowable

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600

December 18, 2006

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